Group II. Claims 20-35, 50-52, 55-57, 59, 61, 65 and 67-70, drawn to a polypeptide and a method for immunizing.

Group III. Claims 62 and 71, drawn to a method of detecting antibodies.

Group IV. Claims 63 and 64, drawn to a method of DNA hybridization.

Group V. Claims 66 and 72, drawn to a method of making a protein vaccine.

Group II, claims 20-35, 50-52, 55-57, 59, 61, 65 and 67-70, are elected, with traverse, for further prosecution in this application. The traverse is as follows:

It is respectfully requested, for the following reasons, that the restriction requirement be reconsidered and withdrawn and that the Examiner conduct a complete search, examination and prosecution of the subject matter claimed in Groups I-V—as they all relate to a single inventive concept, i.e., there is unity of invention, and there is no undue or serious burden in searching and examining all of the claims of Groups I-V.

The Office Action contends that the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the following reasons:

The special technical feature of Groups I and IV is DNA and of Groups II, III and V is the polypeptide. Further, Groups I-V are different combinations of different categories of claims.

More specifically, the Office Action asserts that under Rule 13.1, an applicant is entitled to an independent claim for a use of the product in addition to an independent claim for a given product (DNA and peptide of the instant case).

However, the Office Action further asserts that in the instant case, the claims for a use are: a method of making a peptide (Group I), a method of making an immunization using the peptide (Group II), a method of DNA hybridization (Group IV), a method of an immunoassay (Group III), and a method for formulating a vaccine (Group V).

Under 35 U.S.C. § 121, if there are two or more independent and distinct inventions in one application, the application may be restricted to one of the inventions. Inventions are "independent" if there are no distinct relationships between two, even with patentably distinct inventions, restriction is not required unless one of the following is present (MPEP 808.02):

1 Separate classification;

2. Separate status in the art; or

3. Different field of search.

Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Further, to search or examine these Groups together does not pose a serious burden on the Examiner. It is respectfully submitted that any search of the polypeptide fragments, vaccines, combination vaccines, diagnostic compositions, methods of immunizing, and diagnostic kit of the Group II claims, i.e., any search of the elected Group II subject matter, will encompass: the nucleic acid fragments; the non-borrelial vector, the live vaccine, the vaccine, the diagnostic composition and the diagnostic kit of the Group I claims, i.e., the Group I subject matter, as well the method of determining the presence of antibodies of the Group III claims, i.e., the Group III subject matter, the method of determining the presence of nucleic acids of the Group IV claims, i.e., the Group IV subject matter, and the method for the preparation of an immunological composition of the Group V claims, i.e., the Group V subject matter. That is, there is no serious burden to search and to examine Groups I, II, III, IV and V, as the search and examination of Group II will encompass the subject matter of Groups I and III-V .

Moreover, the present application is the National Phase of a PCT application: the search and examination of the related nucleotide and amino acid sequences presented in this application cannot be said to pose a serious or undue burden to the Examiner, as a nucleotide sequence and the protein it encodes have unity of invention. Note that Example 17 of Annex B Part 2 of the PCT Administrative Instructions (Appendix AI of the MPEP) provides:

> Claim 1: Protein X
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Clearly, the subject matter of Groups I and II have unity of invention and should be searched and examined together in this application. The subject matter of Groups IV and V can be included in the search and examinationof Groups I and II, without any serious or undue burden on the Examiner as the method of DNA hybridization clearly fits within the "DNA" subject matter of Group I and the method of making a protein vaccine clearly fits within the "protein" subject matter of Group

II. Accordingly, at the very least, it is respectfully requested that the restriction requirement be reformulated so that Groups I and II or Groups I, II, IV and V, or Groups II and V are searched and examined together in this application.

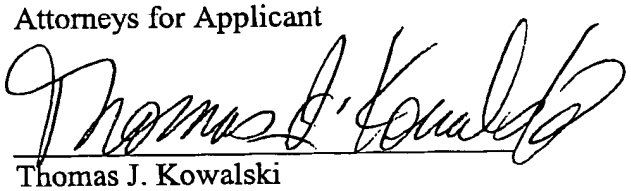
The present 5-way restriction requirement also imposes a severe hardship on both the USPTO and Applicants; namely, overlapping searches and examinations by the USPTO in at least 5 applications, and the need to re-file this application at least four more times, for a total of 5 applications. The cost and expense of the restriction requirement on both the USPTO and Applicants is unduly burdensome; and, for this reason too, the restriction requirement should be reconsidered and withdrawn or at least reformulated.

In sum, Groups I, II, III, IV and V can be searched and examined in this application as there is no undue or serious burden in searching and examining these claims together; and, there is clearly unity of invention between Groups I and II or among Groups I, II, IV and V or among Groups II and V. Thus, the restriction requirement is improper and should be reconsidered and withdrawn or at least reformulated, e.g., so that Groups I and II, or Groups I, II, IV and V, or Groups II and V are searched and examined together in this application (since making a protein vaccine of Group V clearly fits with the search and examination of elected Group II).

In view of the above, reconsideration and withdrawal of the Requirement for Restriction or a reformulation of the Groups, are respectfully requested. As this paper is being filed within the one month time period set forth in the September 20, 2001 Office Action, it is believed that no fee is due for entry and consideration of this response. However, if any fee is determined to be due for entry of this response, the Commissioner is authorized to charge the fee therefor or credit any overpayment in fees to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicant

By: 

Thomas J. Kowalski
Reg. No. 32,147
Tel (212) 588-0800
Fax (212) 588-0500
Email TKowalski@FLHLaw.com